

**Food and Drug Administration  
Center for Biologics Evaluation and Research  
Vaccines and Related Biological Products Advisory Committee Meeting  
May 7, 2010  
Hilton Hotel, Gaithersburg, MD  
DRAFT AGENDA**

**Open Session**

**Topic 1: Finding of PCV DNA Sequences in Rotavirus Vaccines**

8:00 a.m.	Call to Order and Opening Remarks Conflict of Interest Statement	Jack Stapleton, M.D., Chair Christine Walsh, R.N., FDA
8:10	FDA Introduction/Presentation of Issues for Discussion	Norman W. Baylor, Ph.D., FDA
8:20	FDA Safety Update for Rotavirus Vaccine	Wei Hua, M.D., Ph.D., FDA
8:30	Update on Rotavirus Disease and the Impact of Rotavirus Vaccines	Umesh Parashar, M.D., M.P.H., CDC
8:45	GSK Assessment of PCV	Barbara Howe, M.D. Leonard Friedland, M.D. Emmanuel Hanon, Ph.D. Gary Dubin, M.D.
9:45	Porcine Circovirus: An Overview	Gordon Allan, Ph.D., Queen's University Belfast
10:05	Break	
10:20	CBER Assessment of PCV	Phil Krause, M.D., FDA
11:00	Open Public Hearing	
11:30	Committee Discussion: PCV1 in Rotarix	
12:30 p.m.	Lunch	

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**Topic 2: Advanced Analytical Methods in the Characterization of Cell Substrates**

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|------|---|-------------------------|
| 1:30 | Characterization of Cell Substrates Used<br>in the Production of Viral Vaccines<br>for Human Use and Summary of New<br>Technologies | Keith Peden, Ph.D., FDA |
| 2:15 | Open Public Hearing   |                         |
| 2:45 | Committee Discussion  |                         |
| 4:30 | Adjourn Meeting   |                         |